LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President

LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, California 95054 USA
Tel: 1-408-855-0061 Info@lumiquick.com
Fax: 1-408-855-0063 www.lumiquick.com

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602006154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Fecal Occult Blood Test Devices QuickProfile Fecal Occult Blood Test Card QuickProfile Fecal Occult Blood Test Strip	 72001 72006

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
H. Pylori Ab/Ag Test Devices	
QuickProfile H. Pylori Antigen Test Card	71020
QuickProfile H. Pylori Antibody Test Card Whole Blood	71024
QuickProfile H. Pylori Antibody Test Card-Serum	71046
QuickProfile H. Pylori Antigen Test Strip	71061
QuickProfile H. Pylori Antibody Serum Test Strip	71064
QuickProfile H. Pylori Antibody WB Test Strip	71086

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO"
S.R.L.
IDNO 1003602006154
SOCIETATEA CU RASPUNDERE LIMITATA

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No: **FM 574919**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2011-10-20
Latest Revision Date: 2017-10-09

Effective Date: 2017-10-20
Expiry Date: 2019-02-28

...making excellence a habit.™

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

STATEMENT

We, "Technology-Standard" Ltd. having a registered office at 116/95, Kalinin Prospekt, Barnaul, 656037, Russia, assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

We declare that the company mentioned above is authorized to register, notify, renew or update the registration of medical devices on the territory of the Republic of Moldova.

"Tecnology-Standart" Ltd
116|95 Kalinin Prospekt
City of Barnaul, 656037, Russia

SRL SANMEDICO
A. Corobceanu street 7A, apt. 9,
Chişinău MD-2012, Moldova

Date: 01.12.2017

Director: Mr. A. [illegible]

Signature: _____

ЗАЯВЛЕНИЕ

Мы, ООО «Технология-Стандарт», имеющее зарегистрированный офис по адресу 116/95, проспект Калинина, г. Барнаул, 656037, Россия, поручают SRL SANMEDICO, имеющую зарегистрированный офис на улице А.Коробчану 7А, кв. 9, Кишинёв MD-2012, Молдова, быть в качестве уполномоченного представителя в соответствии с условиями директивы 98/79/ЕС.

Мы заявляем, что упомянутая выше компания имеет право регистрировать, уведомлять, обновлять или возобновлять регистрацию медицинских изделий на территории Республики Молдова.

ООО Фирма «Технология-Стандарт»
656037 Россия г.Барнаул,
пр-кт Калинина 116/95

SRL SANMEDICO,
г. Кишинёв MD-2012, Молдова
ул. А.Коробчану 7А, кв. 9

Дата: 01.12.2017

Директор: А.[illegible]

Подпись: _____

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: "Technology-Standard" Ltd

Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) *(name, type or model/batch number, etc.)*:

- Kits and reagents for in vitro diagnostics of haemostasis system

see appendix

4) The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL-CA002-2015-34420**

Barnaul, Russia; 2015-03-17
(Place & date of issue (yyyy-mm-dd))

Andrey Momot, Director "Technology-Standard" Ltd
(name, function and signature of manufacturer)

Appendix

Date: 2015-02-09

List of devices.

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«Techplastin-test» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140	Low	13 02 01 01/ 30539	09.02.2015
«SFMC-test» The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma	081, 007	Low	13 02 03 03/ 43421	09.02.2015
«APTT-test» The kit of reagents for the determination of activated partial thromboplastin time	152, 001	Low	13 02 01 02/ 32392	09.02.2015
«Tech-Fibrinogen-test» The kit of reagents for the determination of fibrinogen concentration in blood plasma	324, 094, 225	Low	13 02 02 01/ 30541	09.02.2015
«ChromoTech-Plasminogen» The kit of reagents for the determination of plasminogen concentration in blood plasma	092	Low	13 02 05 05/ 30578	09.02.2015

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN code

"SANMEDICO" S.R.L. IDNO 1003602008154

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«ChromoTech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Plasma-control» The kit of control blood plasma for the study of haemostasis	400	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII-test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-El-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	012	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» Pathologic plasma	013	Low	13 02 50 02/ 32394	09.02.2015
«Techplastin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	144	Low	13 02 01 01/ 30539	09.02.2015
«Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of XIIa-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003600008154
SOCIETATE IMITATA

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«MultiTech-Fibrinogen» The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers	711, 712	Low	13 02 02 01/ 30541	09.02.2015
«Fibrinogen-Calibrator» The kit of calibrators for the determination of fibrinogen concentration	714	Low	13 02 50 02 / 39413	09.02.2015
«ADP» The kit of reagents for the determination of ADP-aggregation of platelets	030	Low	13 02 04 01/ 30569	09.02.2015
Ristomycin The kit of reagents for the determination of ristomycin-aggregation of platelets	197	Low	13 02 04 01/ 30569	09.02.2015
«Collagen» The kit of reagents for the determination of collagen-aggregation of platelets	095	Low	13 02 04 01/ 30569	09.02.2015
«Adrenaline» The kit of reagents for the determination of adrenaline-aggregation of platelets	031	Low	13 02 04 01/ 30569	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«Aggrescreen-test» The kit of reagents for the express assessment of platelet haemostasis	010	Low	13 02 04 01/ 30569	09.02.2015
«Human platelets»	132	Low	13 02 04 01/ 32409	09.02.2015
«Sodium citrate» A reagent for the stabilization of blood in the study of haemostasis	028	Low	13 02 80 02/ 0	09.02.2015

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO"
S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SNAS
Reg. No. 305/Q-054

ЗЕС®
International

СЕРТИФИКАТ

Настоящий сертификат удостоверяет, что Система Менеджмента Качества организации

ООО Фирма «Технология-Стандарт»

656037, Россия, Барнаул, проспект Калинина 116 / 95

соответствует требованиям стандарта систем менеджмента качества

EN ISO 13485:2012

(ISO 13485:2003 + Cor 1:2009)

в области:

РАЗРАБОТКА, ПРОИЗВОДСТВО И РЕАЛИЗАЦИЯ ДИАГНОСТИЧЕСКИХ НАБОРОВ И РЕАГЕНТОВ ДЛЯ IN VITRO ДИАГНОСТИКИ СИСТЕМЫ ГЕМОСТАЗА

Сертификат N°: M-0379/16 **Дата выставления: 05.08.2016** **Дата регистрации: 05.08.2016**

Этот сертификат, при условии постоянного успешного функционирования Системы Менеджмента Качества организации, действителен до: **01.03.2019**. По вопросам действия сертификата звоните по тел.: +421 (0)2 5831 8343.

Dr. Katarína Srdošová
Руководитель Органа по сертификации

КОПИЯ ВЕРНА
ООО Фирма "Технология-Стандарт"
директор А.П. Момот

Выставил: ЗЕС International a.s., Hraničná 18, 821 05 Bratislava, Словацкая Республика

ACON
YourTrustedPartner

San Diego July 11th, 2018

We, ACON Laboratories Inc. having a registered office at 10125 Mesa Rim Road. San Diego, CA 92121, USA assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

ACON reserves the right to cancel this authorization at any time with a one month notice. If this is the case, ACON will honor any obligation to supply to our representative SanMedico SRL all the products distribution acquired or in the process of being acquired in Public Price bids and Public Tenders process.

Sincerely,

ACON LABORATORIES, INC.

Jassy Alvarenga

Account Manager, International Sales

ACON Laboratories

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Manufacturer: **ACON Laboratories, Inc.**
10125 Mesa Rim Road
San Diego CA 92121
USA

EC-Representative: **Medical Device Safety Service GmbH**
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies): **In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17743EXT01

Valid from: 2017-09-13
Valid until: 2022-09-12

Date, 2017-08-30

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)
No. V1 17 08 80997 017

Model(s): **For Detail Models see attachment**

Facility(ies): **ACON Laboratories, Inc.**
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

For the product(s)/product category (ies):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit,
Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit,
Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit,
CMV IgM EIA Test Kit,

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

Total PSA EIA Test Kit,
PT Coagulation Monitoring System (CCM-121),
PT Coagulation Test Strips (CCS-121),
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream

Munich, MHS-CRT, 2017-08-30

Stefan Preiß

Certification Medical Technology

A1 / 04.11

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany TÜV®

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Test Kits and Related Instruments, Lancet and Lancing Device**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1610619

Valid from: 2016-07-15
Valid until: 2019-07-14

Date, 2016-07-08

Stefan Preiß

Page 1 of 1

DAkkS

DAkkS CRT2 / 10.13

Atlas Medical

Date: 30/06/2018

STATEMENT

We, **Atlas Medical** having a registered office at William James House, Cowley Road, Cambridge, CB4 0WX, UK assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On behalf of the Manufacturer
General Manager
Haya Amawi

30/6/2018

Atlas Medical
...omestic Products

Head Office William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom.
Tel: +44 (0) 1223 858910, Fax: +44 (0) 1223 858524
Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Atlas Medical

King Abdullah II Industrial Estate, Street No. 19, Sahab Free Zone Area, Amman, 11512, Jordan

has been approved by LRQA to the following standards:

ISO 13485:2003

Basem Obaid - Area Operations Manager

Issued By: Lloyd's Register EMEA

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current Issue Date: 23 March 2018
Expiry Date: 31 March 2019
Certificate Issue Number: 10067833

Original Approvals:
ISO 13485 28 February 2009

Approval Certificate Number: ISO 13485 – 0046833

The scope of this approval is applicable to:
ISO 13485:2003
Design Manufacturing and Supply of Medical Diagnostic Reagents and Kits

UKAS MANAGEMENT SYSTEMS
001

REPUBLICA MOLDOVA, mun. CHIȘINĂU, SOCIETATEA PENTRU CONTRACTE ȘI FACTURI, "SANMEDICO" S.R.L.

Declaration Ref No: DC11-0051

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2003) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2012 , EN ISO 13532: 2002, EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
William James House, Cowley Rd.,
Cambridge, CB4 0WX, UK

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	December.2011	21st of March,2018		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Catalouge No	Description
Latex Kits	
8.00.00	CRP latex Kits
8.00.01	CRP latex Kits with buffer
8.00.02	ASO latex Kits
8.00.03	ASO latex Kits with buffer
8.00.04	RF Latex Kits
8.00.05	RF Latex Kits with buffer
8.00.07	hCG Latex Kits
8.00.08	IM (Hourse Stroma)Latex Kits
8.00.11	SLE Latex kits
8.00.12	Staphylococcus Latex Kits
8.00.13	Streptococcus Latex kits
8.00.15	E.Coli Latex Kits
8.00.16	Rota Virus Latex Kits
8.00.17	D-Dimer Latex kits
8.00.21	Waaler rose Latex Kits
Febrile Antigen Kits	
8.01.00	Brucella Rose Bengal
8.01.01	Salmonella OA Reagent
8.01.02	Salmonella OB Reagent
8.01.03	Salmonella OC Reagent
8.01.04	Salmonella OD Reagent
8.01.05	Salmonella HA Reagent
8.01.06	Salmonella HB Reagent
8.01.07	Salmonella HC Reagent
8.01.08	Salmonella HD Reagent
8.01.10	Brucella Abortus Reagent
8.01.11	Brucella Melitensis Reagent
8.01.12	Proteus OX2 Reagent
8.01.13	Proteus OX19 Reagent
8.01.14	Proteus OXK Reagent
8.01.15	Brucella Antigens Kits
8.01.16	Salmonella Antigen Sets
8.01.17	Febrile Antigen Set (10 Antigens)
8.01.17	Febrile Antigen Set (10 Antigens) With controls
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with controls
8.01.19	Febrile Antigens Positive Control
8.01.20	Febrile Antigens Negative Control
Co-aggulation Reagents	
8.02.40	PT Calcium Rabbit Brain Thromboplastin, liquid
8.02.41	APTT (PTT) Micronised Silica Platelet Substitute, Liquid
8.02.60	Normal Coaggulation Control
8.02.61	Abnormal Coaggulation Control
8.02.44	PT Kit
8.02.45	APTT (PTT) Kit

Catalouge No	Description
8.02.48	Calcium Chloride
8.02.69	Fibrinogen Reagent
Hemoglobin Reagents	
8.02.46	Drabkins Reagent, 40x
8.02.50	Hemoglobin Standard, 15g/dL
Sickle Cell Kits	
8.02.67	Sickle Cell Kit
8.02.68	Sickle Cell positive & negative control set
Urine Reagent Strips	
8.03.00	URS 1 Parameter: Glucose
8.03.01	URS 1 Parameter: Protein
8.03.02	URS 1 Parameter: Ketone
8.03.03	URS 2 Parameters:Glucose,Ketone
8.03.04	URS 2 Parameters:Glucose, Protein
8.03.05	URS 2 Parameters: Urobilinogen, Bilirubin (Liver Function Test)
8.03.06	URS 3 Parameters: Protein, pH, Glucose
8.03.07	URS 3 Parameters:Glucose, Protein, Ketone
8.03.15	URS 9 Parameters:Nitrite, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.16	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.17	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.03.18	URS 11 Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
Fertility Rapid Tests	
8.04.00	hCG Test Cassette, Urine
8.04.01	hCG Test Cassette, Urine/Serum
8.04.04	hCG Test Strip, 5.0mm, Urine
8.04.05	hCG Test Strip, 3.5mm, Urine
8.04.06	hCG Test Strip, 2.5mm, Urine
8.04.10	hCG Test Strip, 5.0mm, Urine/Serum
8.04.12	hCG Test Strip, 2.5mm, Urine/Serum
8.04.88	hCG Test Strip, 3.5 mm, Urine/Serum
8.04.90	hCG Test Strip, 2.5 mm, Urine/Serum
8.04.14	LH Test Cassette, Urine
8.04.15	LH Test Strip, 3.5mm, Urine
Infectious Disease Rapid Test - Antibody Testing	
8.04.20	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602005154

ЗАО «ЭКОлаб»142530 Московская обл, г.Электрогорск, ул.Буденного, д.1
e-mail: sekretar@ekolab.ru, Сайт : www.ekolab.ru
Тел: (49643) 3-1374, 3-2311, факс (49643) 3-3143

ЭКОлаб

ИНН: 5035025076, КПП: 503501001
Банк получателя: ПАО Сбербанк России г. Москва
в Орехово-Зуевском ОСБ № 1556/063
р/с 40702810040310124002
к/с 30101810400000000225
БИК 044525225

21.03.2018

АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

Закрытое акционерное общество «ЭКОлаб» (Россия, 142530, Московская обл., г.Электрогорск, ул.Буденного, д.1) настоящим подтверждаем , что "SANMEDICO"SRL (ул. Коробчяну 7А, кв. 9, г. Кишинёв, Республика Молдова) является нашим эксклюзивным дистрибьютором в Республике Молдова и осуществляет участие с продукцией ЗАО «ЭКОлаб» в процедурах государственных закупок товаров на территории Республики Молдова, от своего имени ведет переговоры, представляет коммерческие предложения, заключает соответствующие договоры, а также осуществляет поставки указанной продукции на территории Республики Молдова.

Полномочия по настоящему авторизационному письму не могут быть переданы другим лицам.

Настоящее письмо действительно с момента подписания и до 31 декабря 2018г.

Генеральный директор Борисов В.Ю.

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Certificat

Certificate

N° 2007/28641.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

EKOlab **ZAO «EKOlab»** ЭКОлаб
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS AND OF FINISHED MEDICINE

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ И ЛЕКАРСТВЕННЫХ СРЕДСТВ

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 9001 : 2015

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А

This certificate is valid from (year/month/day):
Данный сертификат действителен с (год/ месяц/ день) **2016-02-21** until / до **2019-02-21**

Managing director of AFNOR Certification
Генеральный директор AFNOR certification

F.LEBEUGLE

11, rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - www.afnor.org

afnor CERTIFICATION

Certificat

Certificate

N° 2007/28642.4

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

EKOlab **ZAO «EKOlab»** ЭКОлаб
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ.

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485 : 2003

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А

This certificate is valid from (year/month/day):
Данный сертификат действителен с (год/ месяц/ день) **2016-02-21** until / до **2019-02-21**

Managing director of AFNOR Certification
Генеральный директор AFNOR certification

F.LEBEUGLE

11, rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - www.afnor.org

afnor CERTIFICATION

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003502009154
CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **CJSC EKOlab**

Address: 1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) **Product(s)** *(name, type or model/batch number, etc.)*:

- Rabbit plasma

4) **The product(s) described above is in conformity with:**

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : pending

Elektrogorsk, Russia; 2017-11-03 ----------

V.Y. Borisov, General Director, CJSC EKOlab

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Appendix

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	Code: EMDS/GMDN	First date of CE-compliance
Rabbit plasma		Low risk	15011290/0	2017-11-08

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN Code

REPUBLICA MOLDOVA, mun. CHISINAU, PENTRU CONTRACTE SI FACTURI, "SANMEDICO" S.R.L., IDNO 1003602008154, SOCIETATEA CU RASPUNDERE LIMITATA

SYNTESYS®

Cert. N.7111/1 Cert. N.6574/1

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

AUTHORIZATION LETTER

We, **Syntesys S.A.S.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/CE and 93/42/CE.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Teolo, 02.01.2018

SYNTESYS S.A.S.
DI RINALDO R &C
Via G. GALILEI 11. 10/3
Z.I. SELVE 35037 TEOLO (PD) - CF. P.I. 03573950288
TEL. 049/9903866 R.A. - FAX 049/9903867

Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.A.S.

REPUBLICA MOLDOVA, mun. CHIŞINĂU
SOCIETATEA CU RĂSPUNDERE LIMITATĂ
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO"
IDNO 1003602006154

SYNTESYS

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione degli articoli prodotti/*Description of Manufacturer*	Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urine. *Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm & 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.*

SYNTESYS

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

Materiale/*Material*	Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato *Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate*

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnotic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

which fulfils the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on:	**2018-06-04**
First issued on:	**2014-06-21**
Expires on:	**2019-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-93779

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey, YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_03_EN

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2018-06-04**
First issued on:	**2013-06-05**
Expires on:	**2019-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-83562

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

REPUBLICA MOLDOVA, mun. CHIȘINĂU PENTRU CONTRACTE ȘI FACTURI "SANMEDICO" S.R.L. IDNO 1003602008154

0774CM_03_EN

HIMEDIA®
For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 01st December 2017

STATEMENT

We, **HiMedia Laboratories Pvt. Ltd.**, having a registered office at A-516, Swastik Disha Business Park, Via Vadhani Industrial Estate, L.B.S. Marg, Mumbai – 400 086, INDIA, assign **SRL SANMEDICO** having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

For HIMEDIA LABORATORIES PVT. LTD.,

HIMEDIA LABORATORIES PVT. LTD. Himedia

Mr. V.M.WARKE.

DIRECTOR – SALES & MARKETING

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6116 9797 / 2500 1607 | Fax : 00-91-22-2500 2286
CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6147 1919 / 2500 3747 | Fax : 00-91-22-6147 1920 / 2500 5764 | Email : info@himedialabs.com
Web : www.himedialabs.com

ISO 9001-2015 CERTIFIED ISO 13485-2012 CERTIFIED WHO GMP CE

"SANMEDICO" S.R.L.

• • • expect only quality from us™

CIN : U85195MH1982PTC028194

REPUBLICA MOLDOVA, mun. Chişinău, PENTRU CONTRACTE ŞI FACTURI, IDNO 1003602008154

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **HiMedia Laboratories Pvt. Ltd.**

Address: 23 Vadhani Industrial Estate,LBS Marg, Mumbai - 86, MS, India

and

2) European authorized representative: **CEpartner4U BV,**

Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) *(groupnames /.)*:

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants,Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J.Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs	NL-CA002-2013-26445	5
CCM	Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits ,Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid	NL-CA002-2013-26446	6
MBP	Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits	NL-CA002-2013-26447	7

type and model numbers: see appendix

4) The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Mumbai, India; 2018-30-10

(Place & date of issue (yyyy-mm-dd))

Dr. G.M.Warke , Managing Director

(name; function and signature of manufacturer)

qualityaustria
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CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **quality**austria certificate to the following organisation:

This **quality**austria certificate confirms the application and further development of an effective

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HiMedia Laboratories Pvt. Ltd.
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Ghatkopar (W), Mumbai - 400086, Maharashtra, India

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori,
Nashik - 422 022, Maharashtra, India

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Diffrentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

Registration No.: 17285/0

Date of initial issue: 29 December 2015

Valid until: 21 November 2020

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IQNet

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Specialist representative

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

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98d03225-796f-4e13-a446-6a70d9a39774

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"SANMEDICO" S.R.L.
IDNO 1003602006154
SOCIETATEA CU RASPUNDERE LIMITATA

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23, Vadhani Industrial Estate L.B.S.Marg,
Ghatkopar (W), Mumbai - 400086, Maharashtra, India

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori, Nashik - 422 022, Maharashtra, India

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
EN ISO 13485:2012
Medical devices - Quality management systems - Requirements for regulatory purposes

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Diffrentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

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Registration No.: 00275/0
Date of initial issue: 21 November 2017
Valid until: 31 March 2019

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IQNet

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Ing. Andreas Aichinger, MSc
Specialist representative

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Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is approved by the VDA (Association of the Automotive Industry).

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S.R.L.
IDNO 1003602006154
SOCIETATE CU RĂSPUNDERE LIMITATĂ

CERTIFICATE

Quality Austria Central Asia Private Limited
(A Division of Peacock Global Company)
Awards this Certificate to

HiMedia Laboratories Pvt. Ltd.
Unit I : B/4-6, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India
Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombivli, District Thane – 421 204, Maharashtra, India
Unit III : D-61 MIDC, Phase-II, Near Shani Mandir, Dombivli, District Thane – 421204, Maharashtra, India

This Certificate confirms the application and further development of an effective

WHO GMP Compliance System

Complying with the requirement of

WHO GMP Guidelines

Unit I : Manufacture & supply of Biosciences products for applications in Microbiology (includes Dehydrated Culture Media, Culture Media Bases, Antimicrobial Susceptibility Systems & Bacteriological Differentiation Aids), Animal Cell Culture, Plant Tissue Culture and Molecular Biology
Unit II : Manufacture and supply of Sterile Ready Prepared Media
Unit III : Manufacture and supply of Sterile Ready Prepared Media

Report No.:QACA/WHO/069
Issue Date: 21/12/2016
Expiry Date: 20/12/2019

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

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India: 20 Dec 2016
Quality Austria Central Asia Private Limited (A division of Peacock Global company)

Alok Kumar
Country Head

The Product and Systems Liability rests with the manufacturer and under no circumstances Quality Austria Central Asia Shall be Held Responsible

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